SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 100—GENERAL

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AUTHORITY: 21 U.S.C. 321, 331, 337, 342, 343, 348, 371.

SOURCE: 42 FR 14306, Mar. 15, 1977, unless otherwise noted.

Subpart A—State and Local Requirements

§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) *Scope and purpose.* (1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption. The agency may grant the exemption, under such conditions as it may prescribe by regulation, if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.

(b) *Definitions.* (1) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

(2) *Agency* means the Food and Drug Administration.

(3) *Commissioner* means the Commissioner of Food and Drugs.

(4) *State* means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) *State requirement* means any statute, standard, regulation, or other requirement that is issued by a State.

(c) *Prerequisites for petitions for exemption from preemption.* The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a)(3) through (a)(5) of the act submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to

the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quality, and fill. ''Not identical to'' does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) *Form of petition.* (1) All information included in the petition should meet the general requirements of § 10.20(c) of this chapter.

(2) An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.)

(3) Petitions for exemption from preemption for a State requirement shall be submitted to the Dockets Management Branch in the following form:

(Date) _____
Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
rm. 1–23, 12420 Parklawn Dr.,
Rockville, MD 20857.

PETITION REQUESTING EXEMPTION FROM PREEMPTION FOR STATE REQUIREMENT

The undersigned submits this petition under section 403A(b)of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (*identify State or political subdivision of the State*) because (*document petitioner's authority to submit petition on behalf of the State*).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.

D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner's action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB number 0910–0277)

(e) *Submission of petition for exemption; public disclosure.* The availability for public disclosure of a petition for exemption will be governed by the rules specified in § 10.20(j) of this chapter.

(f) *Agency consideration of petitions.* (1) Unless otherwise specified in this section, all relevant provisions and requirements of subpart B of part 10 of this chapter, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act.

(2) If a petition does not meet the prerequisite requirements of paragraph (c) of this section, the agency will issue a letter to the petitioner denying the petition and stating in what respect the petition does not meet these requirements.

(3) If a petition appears to meet the prerequisite requirements in paragraph (c) of this section, it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(4) Any interested person may submit written comments to the Dockets Management Branch on a filed petition as provided in § 10.30(d) of this chapter.

(5) Within 90 days of the date of filing the agency will furnish a response to the petitioner. The response will either:

(i) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that it intends to publish in the FEDERAL REGISTER a proposal to grant the exemption through rulemaking;

(ii) Deny the petition and state the reasons for such denial; or

(iii) Provide a tentative response indicating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

(g) If a State submitted a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

[58 FR 2468, Jan. 6, 1993]

§ 100.2 State enforcement of Federal regulations.

(a) Under section 307 of the Federal Food, Drug, and Cosmetic Act (the act), a State may bring, in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) of the act if the food that is the subject of the proceedings is located in the State.

(b) No proceeding may be commenced by a State under paragraph (a) of this section:

(1) Before 30 days after the State has given notice to the Food and Drug Administration (FDA) that the State intends to bring such proceeding.

(2) Before 90 days after the State has given notice to FDA of such intent if

FDA has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding.

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

(c) A State may intervene as a matter of right, in any court proceeding described in paragraph (b)(3) of this section.

(d) The notification that a State submits in accordance with paragraph (b) of this section should include the following information and be submitted in the following recommended format:

(Date) _____
Name of State agency _____
Post office address _____
Street address _____
City, State, and ZIP code _____
Name of product(s) covered by the notification _____
Reporting official, title, and telephone no. _____
FAX No. _____
Agency contact (if different from reporting official), title, and telephone no. _____

Director,
Division of Enforcement (HFS–605),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204.

To Whom It May Concern:

The undersigned, _____, submits this letter of notification pursuant to section 307(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337(b)(1)) with respect to _____. (name of products covered by the notification and the enforcement action that is to be initiated)

Attached hereto, and constituting a part of this letter of notification are the following:

A. The name of the product.

B. The type and size of each product container.

C. Copy of the label and labeling of the product.

D. Manufacturing code (if applicable).

E. Name and address of firm believed to be responsible for violations.

F. Name and address of parent firm (if known).

G. Reason for the anticipated State enforcement action (list specific violations, including sections of the law violated).

H. Name of firm against which action is anticipated (if applicable).

I. Type of enforcement action.

Yours very truly,
Reporting Agency
By _____
(Indicate authority)

(e) The letter of notification should be signed by a State official authorized by the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Enforcement (HFS–605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX number 202–205–4642.

(g) FDA will notify the State of the date in which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS–605) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Enforcement, Office of Field Programs, Center for Food Safety and Applied Nutrition, FDA, will respond to the State's notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(i) Information contained in State notification letters shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§ 20.61, 20.64, and 20.88 of this chapter.

(j) *Definitions.* (1) *Informal enforcement actions* include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question.

(2) *Formal enforcement actions* include seizures, injunctions, or other civil judicial enforcement actions that pertain to the food in question. (Information collection requirements in this section

were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0275.)

[58 FR 2460, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993]

Subparts B–E [Reserved]

Subpart F—Misbranding for Reasons Other Than Labeling

§ 100.100 Misleading containers.

In accordance with section 403(d) of the act, a food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading.

(a) A container that does not allow the consumer to fully view its contents shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill. Slack-fill is the difference between the actual capacity of a container and the volume of product contained therein. Nonfunctional slack-fill is the empty space in a package that is filled to less than its capacity for reasons other than:

(1) Protection of the contents of the package;

(2) The requirements of the machines used for enclosing the contents in such package;

(3) Unavoidable product settling during shipping and handling;

(4) The need for the package to perform a specific function (e.g., where packaging plays a role in the preparation or consumption of a food), where such function is inherent to the nature of the food and is clearly communicated to consumers;

(5) The fact that the product consists of a food packaged in a reusable container where the container is part of the presentation of the food and has value which is both significant in proportion to the value of the product and independent of its function to hold the food, e.g., a gift product consisting of a food or foods combined with a container that is intended for further use after the food is consumed; or durable commemorative or promotional packages; or

(6) Inability to increase level of fill or to further reduce the size of the package (e.g., where some minimum package size is necessary to accommodate required food labeling (excluding any vignettes or other nonmandatory designs or label information), discourage pilfering, facilitate handling, or accommodate tamper-resistant devices).

(b) [Reserved]

[59 FR 537, Jan. 5, 1994]

Subpart G—Specific Administrative Rulings and Decisions

§ 100.155 Salt and iodized salt.

(a) For the purposes of this section, the term *iodized salt* or *iodized table salt* is designated as the name of salt for human food use to which iodide has been added in the form of cuprous iodide or potassium iodide permitted by §§ 184.1265 and 184.1634 of this chapter. In the labeling of such products, all words in the name shall be equal in prominence and type size. The statement ''This salt supplies iodide, a necessary nutrient'' shall appear on the label immediately following the name and shall be in letters which are not less in height than those required for the declaration of the net quantity of contents as specified in § 101.105 of this chapter.

(b) Salt or table salt for human food use to which iodide has not been added shall bear the statement, ''This salt does not supply iodide, a necessary nutrient.'' This statement shall appear immediately following the name of the food and shall be in letters which are not less in height than those required for the declaration of the net quantity of contents as specified in § 101.105 of this chapter.

(c) Salt, table salt, iodized salt, or iodized table salt to which anticaking agents have been added may bear in addition to the ingredient statement designating the anticaking agent(s), a label statement describing the characteristics imparted by such agent(s) (for example, ''free flowing''), providing such statement does not appear with greater prominence or in type size larger than the statements which immediately follow the name of the food as required by paragraphs (a) and (b) of this section.

(d) Individual serving-sized packages containing less than ½ ounce and packages containing more than 2½ pounds

of a food described in this section shall be exempt from declaration of the statements which paragraphs (a) and (b) of this section require immediately following the name of the food. Such exemption shall not apply to the outer container or wrapper of a multiunit retail package.

(e) All salt, table salt, iodized salt, or iodized table salt in packages intended for retail sale shipped in interstate commerce 18 months after the date of publication of this statement of policy in the FEDERAL REGISTER, shall be labeled as prescribed by this section; and if not so labeled, the Food and Drug Administration will regard them as misbranded within the meaning of sections 403 (a) and (f) of the Federal Food, Drug, and Cosmetic Act.

[42 FR 14306, Mar. 15, 1977, as amended at 48 FR 10811, Mar. 15, 1983; 49 FR 24119, June 12, 1984]

PART 101—FOOD LABELING

Subpart A—General Provisions

Sec.

Subpart B—Specific Food Labeling Requirements

Subpart C—Specific Nutrition Labeling Requirements and Guidelines

Subpart D—Specific Requirements for Nutrient Content Claims

Subpart E—Specific Requirements for Health Claims